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(54) Dilator

(57) A dilator is formed from an elongated tube (12) having a longitudinally extending hollow bore (14) therethrough, a connector at one end for connection to a fluid supply, and a terminator (18) at the other end carrying an inflatable, inelastic, multi-lobed casing (20) secured at the proximal and distal ends, respectively, of the terminator for inflation through the hollow bore of the tube. A cup-shaped flange (30) at the proximal end of the terminator surrounds the proximal attachment of the casing and positions the maximum diameter of the casing at the termination of the rim of the flange. A multi-lobed construction of the casing provides a wrinkle-free surface when the casing is deflated.

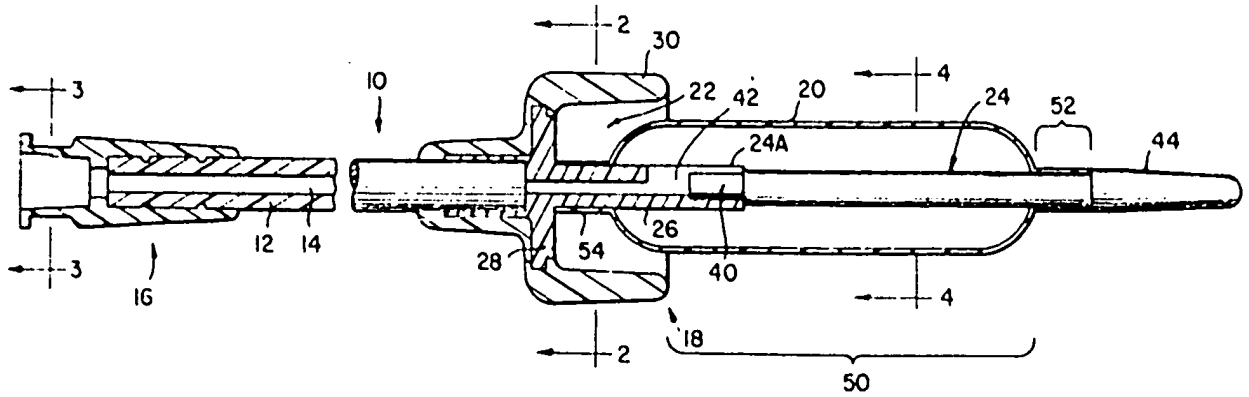

Fig. 1

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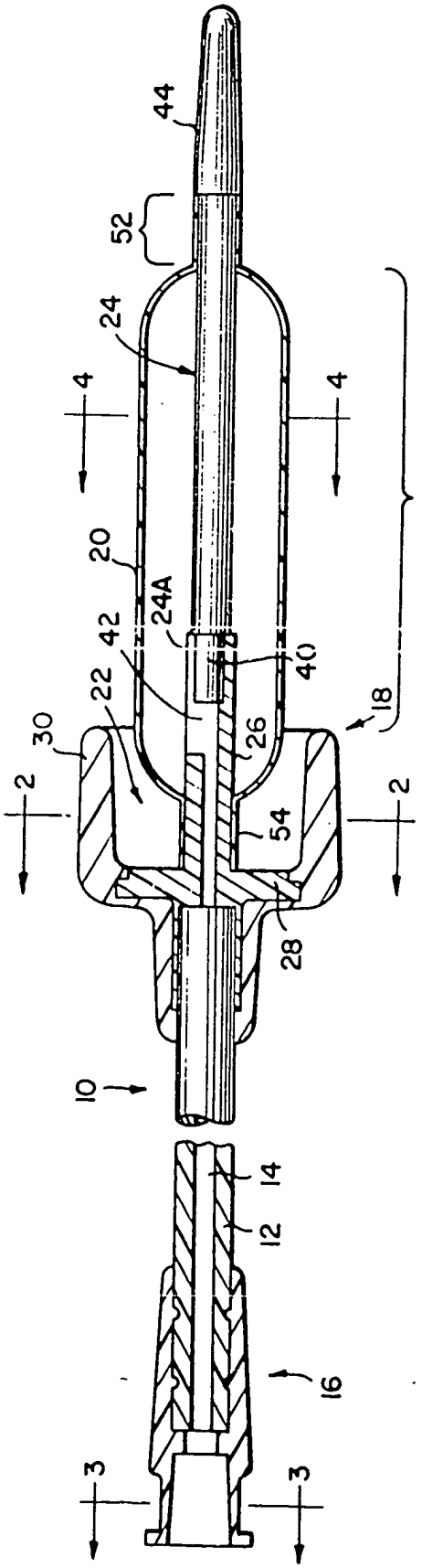

Fig. 1

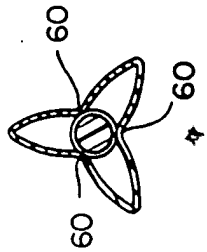

Fig. 5

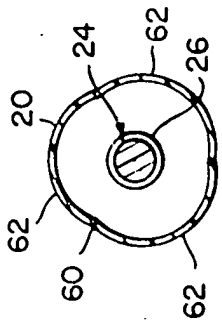

Fig. 4

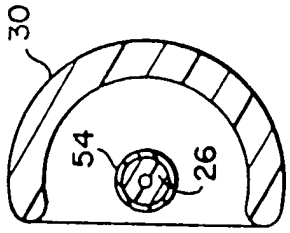

Fig. 2

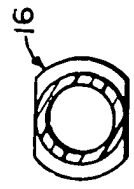

Fig. 3

SPECIFICATION

Dilator

The invention relates to a dilator and, more particularly, to a dilator using an inflatable element and is particularly appropriate for use as a cervical dilator.

Dilators are commonly used in medical examination and treatment to obtain access to interior portions of the body through an orifice for that purpose. A variety of dilators are commonly used. One type of dilator comprises a series of rigid rods of increasing diameter which are successively positioned in the orifice to thereby enlarge it. Dilators of this type require precise and skillfull positioning to avoid undue discomfort to the patient.

Expansible or inflatable dilators are also in use. These also require careful positioning and insertion, but are frequently simpler to use and more readily accommodate a variety of conditions and needs.

Illustrative of various types of inflatable dilators that have been proposed are those shown in U.S. Patents Nos. 3900033, 4137922, 3095871, 1735519, 2687789 and 3848602. In some of these, the inflatable element has a bulbous end portion which serves as an anchor against inadvertent removal after inflation but which also, when inflated, establishes longitudinal (axial) forces which shift the position of the device and may also cause discomfort to the patient. In others, the inflatable element is so positioned that at least one end thereof can shift and distort during insertion and may even be ruptured on insertion into a tightly constricted orifice unless sufficient care is taken to prevent this.

According to the present invention there is provided an inflatable dilator including an elongate member with a bore in at least part of its length, a substantially inelastic inflatable thin walled casing surrounding the member and sealingly fixed thereto at each end, the interior of the casing being in communication with the bore, the casing, when inflatable, presenting a central section of substantially constant cross section and end sections tapering towards its ends, and stop means on said member effective as a stop on insertion of the dilator into an orifice to be dilated.

The dilator of the invention is insertable into an orifice with minimal discomfort and allows accurate placement in an orifice to be dilated.

The dilator of the present invention can be formed from an elongated tube having a longitudinal (axial) bore extending therethrough and having, at one end thereof, a connector for attachment to a fluid supply source such as an air tank to be use for inflation. At its other end, this tube is connected to a terminator carrying the inflatable, but inelastic, casing. The casing is in the form of a generally cylindrical sleeve having an enlarged center portion and narrowed end portions. The end portions are secured in fluid-tight attachment, preferably to opposite ends of a rod forming a part of the terminator, and the casing can be inflated through a port from the bore. The mid-portion of the casing is of substantially constant cross-section intermediate the end-attachment portions and preferably has a multi-lobal cross section which presents a substantially wrinkle-free surface during insertion.

A cup-like flange preferably surrounds the terminator rod as the stop means, being preferably oriented such that the rim of the flange is positioned at approximately the beginning of the maximum cross-section of the casing when the casing is inflated. The flange provides a positive stop for positioning the dilator in the orifice and additionally insures that the adjacent end of the casing lies outwardly of the orifice during insertion so that the dilator will now be inadvertently anchored in the orifice at the time of removal.

The flange and/or cup is preferably arcuately discontinuous, that is, it extends circumferentially around the terminating rod by less than 360 degrees, preferably about 300 degrees. This allows visual observation of the casing during its insertion, and allows sighting through the orifice after inflation of the casing and its consequent dilation of the orifice.

The casing is preferably formed in a multi-lobal, preferably tri-lobal, configuration, that is, it has two or more, preferably three, intersecting arcuate sections joined together to form the casing. The radii of the arcuate sections are only slightly smaller than the radius of the corresponding, generally circular cross section of the casing resulting from their joining. This results in a substantially smooth casing of nearly circular cross section when inflated, thereby minimizing discomfort during dilation which might otherwise be caused by irregularities in the casing. When deflated, however, e.g. when the casing is being inserted into the orifice, it assumes a regular, symmetric shape of diminished cross-section that is free of randomly oriented wrinkles; this minimizes discomfort during insertion.

In preferred embodiment of the invention, the terminator rod is formed in two sections, namely, a base portion and a tip portion. The base portion has the form of a hollow-core cylindrical rod from which the flange extends, first outwardly, and then parallel to, and surrounding, the rod and enclosing the major portion of the rod. The tip portion comprises a generally solid rod connectable to the base portion and having a blunted nose at a forward end thereof stepped slightly outwardly of the remainder of the rod. During assembly of the dilator, one end of the casing is slipped over, and subsequently bonded to, the rod portion of the base section. The rod tip is then inserted through the other end of the casing and is attached to the base section. A small amount of adhesive may be applied to this tip, just prior to its insertion through the casing, in order to form a bond to the base. When the tip is so inserted into the base, a forward portion of the new casing, of narrowed diameter, lies snugly against the distal end of the tip and immediately behind the stepped nose thereof. The height of the step is preferably equal to the thickness of the wall of the casing so that, when positoned on the tip, the casing forms a generally smooth, continuous surface with the blunted tip, thus, discontinuities in height are avoided.

The base portion itself may be formed in two parts, the first of which comprises the cylindrical rod

and a portion of the flange, and the second of which comprises the remainder of the flange together with an additional tubular extension for connection to the tube. The latter section may be insert molded on the former.

The invention will be more clearly understood from the following description which is given by way of example only with reference to the accompanying drawings, in which:

Fig. 1 is a cross sectional view of a dilator of the invention showing the construction thereof; and

Figs. 2, 3 and 4 are cross-sectional views taken along the lines 2-2, 3-3 and 4-4, respectively, of Fig. 1.

The dilator 10 illustrated is formed from an elongated, generally cylindrical tube 12 having a central bore 14 extending longitudinally therethrough, a connector 16 at one end thereof, and a terminator 18 carrying an inflatable casing 20 at the other end. The connector 16 is advantageously a standard luer-lock connector which couples to a corresponding fitting on a fluid supply source for application of pressurized fluid to the bore 14.

The terminator 18 comprises a base portion 22 connected at one end thereof to the tube 12, and a tip portion 24 connected to the base portion 22. The base portion has the form of a hollow-core cylindrical rod 26 and a flange comprising a first portion 28 extending outwardly and generally perpendicular to the rod 26, and a second axially oriented portion 30 comprising a wall extending parallel to the rod 26 forward of the transverse portion 28. A further portion 32 of section 30 curves inwardly toward the tubular portion 26 and terminates in a tubular section 38 into which the tube 12 is fitted. A bore 40 extends through the base portion 22 in communication with the bore 14 of tube 12. The bore 40 terminates in a port 42 through which the casing 20 is inflated.

The tip 24 is in the form of an extended rod connected to the distal end of rod 26 and having a blunted nose 44 at its distal end. The nose is stepped outwardly of the remainder of the body of the tip 24 by a distance that is equal to the thickness of the casing 20 so that, when the latter is connected to it, the casing and nose form a generally continuous surface with no significant discontinuities in height.

The casing 20 comprises an elongated, inelastic, inflatable, generally cylindrical tube having a mid-section 50 of substantially constant diameter; end sections 52, 54 of diameter less than that of mid-section 50 and approximately equal to the diameter of the tip 24 and the rod 26 on which they are mounted; and transition sections 56, 58 of increasingly diminished diameter in a direction proceeding outwardly of the mid-section 50.

The casing 20 has a multi-lobal structure and, preferably, a tri-lobal structure. As seen most clearly from Fig. 4, the mid-section of the casing is nearly circular in cross section, but has slight cusps 60 formed by intersecting arcuate sections 62 of slightly smaller radius than that of the overall radius of the casing 20. The difference between the arcuate radii and the overall radius is extremely small (less than a few percent, and preferably much smaller) so that the cross section of the casing 20 is nearly completely circular when inflated. Thus, a substantially smooth surface at all points is presented to the orifice which is being dilated. However, when the casing 20 is in the deflated or collapsed condition, as shown in Fig. 5, the casing 20 collapses symmetrically and uniformly along the longitudinal lines of the cusps 60 and thus presents a uniform aspect, free of random and possibly radially-oriented folds which might cause discomfort during insertion.

The flange 28 functions as a stop and as shown in Fig. 2 is only part of a circle. This allows observation upon insertion of the dilator.

To assemble the dilator, the base section 26 is inserted through the neck 54 of the casing 20. A glue, solvent, or other bond forming material is placed on the base portion in the area in which the neck 54 is to be seated prior to insertion to form a fluid-tight bond therefor. The tip 24 is then similarly coated with a glue, solvent, or other bond-forming material at its proximal end 24A where it is joined to the base 22, and additionally at its distal end immediately behind the blunted nose 44 and is then inserted through the neck 52 of the casing so that end 24A is snugly seated into base 22. The neck 52 of casing 20 is then pressed firmly around the tip 24 and is seated thereon, fluid-tight. Thereafter, section 30 is joined to section 28 to complete assembly of the terminator 18, and tube 12 is inserted into the base to complete assembly of the dilator.

Numerous materials, generally plastics, may be utilized for the dilator here described. However, we have found Lexan to be particularly advantageous for the tube 12, the connector 16 and the terminator 18, and p.v.c. for the casing 20.

The dilator of the invention as described allows positive positioning within an orifice to be dilated, while allowing continued observation of the forward end of the dilator as it is being inserted into the orifice and, indeed, observation into the orifice beyond the dilator. The dilator in at least its preferred forms has an inelastic, inflatable casing of essentially constant diameter throughout the portion in contact with the orifice walls, and has a multi-lobal cross-section departing only slightly from a circular cross-section but sufficient to insure that, when collapsed during insertion, the casing is characterised by longitudinally-extending fold lines and is free of randomly-oriented, particularly radially-extending, fold lines.

CLAIMS

1. An inflatable dilator including an elongate member with a bore in at least part of its length, a substantially inelastic inflatable thin walled casing surrounding the member and sealingly fixed thereto at each end, the interior of the casing being in communication with the bore, the casing, when inflated, presenting a central section of substantially constant cross section and end sections tapering towards its ends, and stop means on said member effective as a stop on insertion of the dilator into an orifice to be dilated.

2. A dilator according to claim 1, wherein said stop means is a cup surrounding the member with its open side facing the casing and the end of the

member intended for insertion.

3. A dilator according to claim 2, wherein one end of the casing is fixed to the member at a position within the cup.

4. A dilator according to claim 3, wherein one end of the central section of the casing is in the region of the open end of the cup in the axial sense of the member.

5. A dilator according to claim 1, wherein the stop means is a flange on the member.

6. A dilator according to claim 2, 3, 4 or 5 wherein the stop means is discontinuous round the member.

7. A dilator according to any preceding claim, wherein the casing has a multi-lobal cross section in said central section.

8. A dilator according to claim 7, wherein the multi-lobal section is tri-lobal.

9. A dilator according to any preceding claim, wherein the end of the member for insertion is blunted and has, adjacent thereto, a radial step substantially equivalent to the thickness of the material of the casing on which the adjacent end of the casing is secured so as to provide a substantially continuous outer surface to the device in the region of the securement.

10. A dilator according to any preceding claim, wherein said member includes a tubular part carrying said stop means and a rod which carries the tip for insertion.

11. A dilator according to claim 10, wherein the rod blocks the end of the bore in the tubular part which has a side port to the interior of the casing.

12. A dilator according to claim 10 or 11, wherein the tubular part carries the or a flange, and the or a cup is on the flange and the cup has a rearward extension to receive the end of a connecting tube.

13. A dilator according to claim 12 with a connecting tube received in the rearward extension.

14. An inflatable dilator constructed and arranged substantially as hereinbefore described with reference to and as illustrated in the accompanying drawings.

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